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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,862	01/30/2002	Michel Gau	HOE-676	6870

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EXAMINER

MILLER, CHERYL L

ART UNIT PAPER NUMBER

3738

DATE MAILED: 02/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/060,862	GAU, MICHEL	
	Examiner	Art Unit	
	Cheryl Miller	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2004.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 10-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-11, 17-24 is/are rejected.
- 7) ☒ Claim(s) 12-16 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 8, 2004 has been entered.

### ***Response to Arguments***

Applicant's arguments with respect to claims 10-24 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 112***

Claims 18 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Independent claim 10 requires a spherical body to protrude from both sides of the cage. Claim 10 also recites, "at least one cage". Claims 18 and 19, which claim the cage to comprise one or two components, contradicts claim 10, since if two components exist, applicant does not have support in the specification or drawings for one spherical body to protrude through two components, so as to protrude from opposite sides of the cage. One possible suggestion to overcome the rejection and clarify the claim would be to change "wherein the cage consists of two substantially identical single components" to recite --wherein the cage consists of two substantially identical single **cages**--, or something along these lines. This way, a spherical body still protrudes from both sides of the cage, and this has proper antecedent basis

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to claim 10, which claims at least one cage. Similar errors occur throughout the claim and in claim 19.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 23 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Buttner-Janz (US 5,556,431). Buttner-Janz discloses a prosthesis (core 3) *adapted* to replace a nucleus of an intervertebral disc (is sized to fit within a nucleus) comprising a cage (rim 5; see attachment 1, seen in red) of substantially planar shape and at least one spherical body (4, see attachment 1, seen in yellow) disposed non-displaceably in the cage (5; body is not displaceable within the cage 5) and freely rotatable (body 4, is rotatable, when rotating, it rotates the entire prosthesis) about its center so as to be movable in two directions in the plane of the cage (movable to rotate clockwise and counter-clockwise), the spherical body (4) made of a substantially rigid, non-oxidizing, biocompatible material (col.2, lines 40-41) and having a diameter greater than the planar thickness of the cage (fig.1), and is adapted to protrude from both opposite sides of the cage in the form of spherical caps (fig.1), and is adapted to fit within the annulus. Buttner-Janz discloses a spherical body which is not elastically deformable (col.2, lines 40-41; fig.1).

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Claims 10, 11, 17, 19, 20, and 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Baumgartner (US 5,755,797, cited by applicant in IDS). Referring to claims 10, 11, 17, 19, and 20, Baumgartner discloses a prosthesis comprising an assembly (fig.6) comprising at least one cage (20+21) and at least one spherical body or ball (7) wherein the assembly has dimensions shaped to fit in a intervertebral nucleus (fig.1, 2; col.1, lines 10-15), the cage (20+21) has a shape elongated in one plane (fig.6), the spherical body (7) is made of a substantially rigid, non-oxidizing, biocompatible material (control rigidity by use of solid members, col.2, lines 13-15; permanently dimensionally stable, col.2, lines 1-4), and is captured non-displaceably in the cage (balls 7 may be held not displaceably by two 21's), freely rotatable about its center (14; col.2, lines 5-9) within the cage (looking at fig.6, balls 7 are captured within the cage, that is they are captured within the outer boundaries of the cage; center ball 7 is captured between two 21's, therefore within the 21's and also, within the ends of 20), and protrudes at opposite sides of the elongated plane of the cage in the form of spherical caps (fig.6). Baumgartner discloses a substantially planar cage that is curved in the plane (wire 20 may be curved) and symmetrical. Baumgartner discloses a cage which may take the shape of an isosceles trapezoid (wire 20 may be bend or curved to this shape) and holds a plurality of spherical bodies (7), located at corners of the cage. Baumgartner discloses a cage (20+21) adapted to fit within the confines of an intervertebral nucleus (col.1, lines 10-15), which may have any diameter (col.4, lines 1-8).

Referring to claims 21-22, Baumgartner discloses a method for implanting a prosthesis (col.1, lines 10-15) comprising making an incision endoscopically in the annulus (4) between two vertebral bodies (fig.1, 3), providing an opening (30) large enough to remove and replace the

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nucleus (col.1, lines 50-54), inserting the above described prosthesis (fig.6), and closing the opening (col.4, lines 37-39), wherein the opening may be closed with a suture (11, even though Baumgartner does not explicitly disclose a suture used to close the opening, it is so well known in the art and is obvious if not inherent to use a suture to close any tissue opening in the body).

Referring to claim 23, Baumgartner discloses a prosthesis (fig.6) adapted to replace a nucleus of an intervertebral disc (col.1, lines 10-15) comprising a cage (20+21) of substantially planar shape and at least one spherical body (7) disposed non-displaceably (may be held tightly between two 21's as to not displace) in the cage (20+21; balls are held in the boundaries of the cage, see above) and freely rotatable about its center (14) so as to be movable in two directions (clockwise and counter-clockwise about 14) in the plane of the cage, the spherical body (7) made of a substantially rigid, non-oxidizing, biocompatible material (control rigidity by use of solid members, col.2, lines 13-15; permanently dimensionally stable, col.2, lines 1-4) and having a diameter greater than the planar thickness of the cage, and is adapted to protrude from both opposite sides of the cage in the form of spherical caps (fig.6), and is adapted to fit within the annulus (fig.1, 2).

Claims 10, 11, 19, 20, 23, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Bristol-Myers Squibb Co (EP 0 577 179 A1). Referring to claims 10, 11, 19, and 20, Bristol-Myers discloses a prosthesis (1) comprising an assembly (fig.1, 2) comprising at least one cage (6) and at least one spherical body or ball (2) wherein the assembly has dimensions shaped to fit in a intervertebral nucleus (fig.1), the cage has a shape elongated in one plane (seen in fig.1), the spherical body (2) is made of a substantially rigid, non-oxidizing, biocompatible material (col.1,

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lines 4-6), and is captured non-displaceably in the cage (fixed locations, col.2, lines 10-18), freely rotatable (rotatable about central bore 3) about its center within the cage (ball 2 is rotatable within the boundaries of the cage; that is as seen in fig. 1, middle ball 2, is within the anterior-posterior confines of cage 6, therefore, balls 2 are within the cage), and protrudes at opposite sides of the elongated plane of the cage in the form of spherical caps (fig.1). Bristol-Myers discloses a substantially planar cage that is curved in the plane and symmetrical (fig.2). Bristol-Myers discloses a cage adapted to fit within the confines of an intervertebral nucleus (fig.1).

Referring to claims 23-24, Bristol-Myers discloses a prosthesis adapted to replace a nucleus of an intervertebral disc (fig.1) comprising a cage (6) of substantially planar shape (fig.1) and at least one spherical body (2) disposed non-displaceably in the cage (fixed locations, col.2, lines 10-18) and freely rotatable (rotatable about 6) about its center (at 3) so as to be movable in two directions in the plane of the cage (clockwise and counter-clockwise movement about 6), the spherical body (2) made of a substantially rigid, non-oxidizing, biocompatible material (col.1, lines 5-7) and having a diameter greater than the planar thickness of the cage (fig.1), and is adapted to protrude from both opposite sides of the cage in the form of spherical caps, and is adapted to fit within the annulus (fig.1). A spherical body which is not elastically deformable is also disclosed (made of metal, col.1, lines 5-7).

***Allowable Subject Matter***

Claims 12-16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 18 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

***Conclusion***

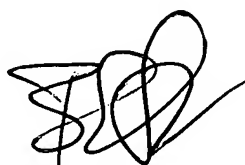
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Cheryl Miller



**BRUCE SNOW**  
**PRIMARY EXAMINER**



Fig. 1

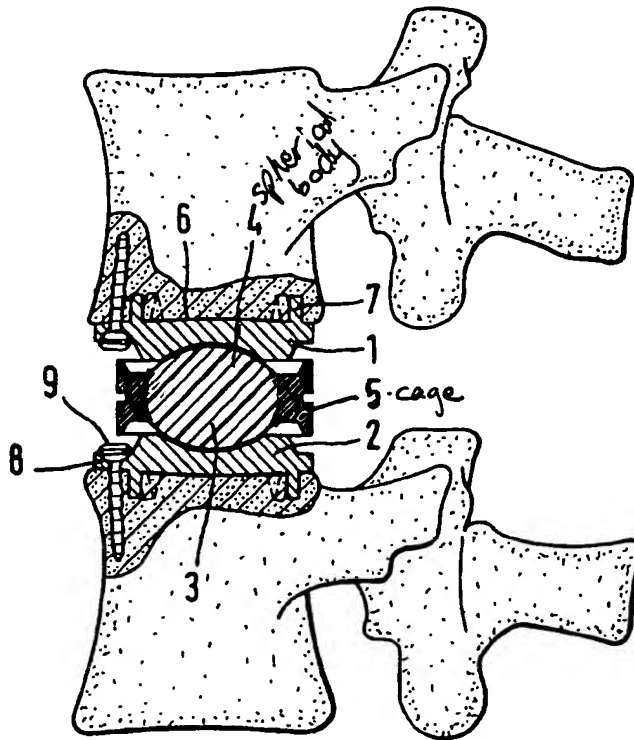


Fig. 2

